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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH,

CENTRAL DIVISION

NUTRACEUTICAL CORPORATION, et al., Plaintiffs, v, LESTER CRAWFORD, DVM, Acting Commissioner of the U.S. Food and Drug Administration, et al., Defendants.	**MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT** **(Oral Argument Requested)** Case No. 2:04CV00409 TC

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This Honorable Court should grant the motion for summary judgment by Plaintiffs Solaray, Inc. and Nutraceutical Corporation ("Plaintiffs'") on Plaintiffs' causes of action one through four,[1] which challenge FDA's Final Rule[2] declaring all dietary supplements containing ephedrine alkaloids (regardless of dose) adulterated[3] and thus illegal to manufacture, hold, distribute, and sell, subject to civil and criminal penalties.[4] FDA's Final Rule, as a matter of law, violates the Food Drug and Cosmetic Act ("FDCA"), as amended by the Dietary Supplement Health and Education Act ("DSHEA"), 21 U.S.C. § 342(f),[5] and also violates the Administrative Procedure Act, 5 U.S.C. §§ 553 and 706 ("APA").

INTRODUCTION

The Final Rule is void under the FDCA because FDA failed to satisfy its burden of proving that dietary supplements containing 10 mg or less ephedrine alkaloids per daily dose pose a "significant or unreasonable risk of illness or injury." 21 U.S.C. § 342(f). Under the FDCA, the FDA may ban a dietary supplement only by proving that it is "adulterated," which

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[1] This case can be resolved in its entirety should the Court find in Plaintiffs favor on its causes of action one through four. Plaintiffs' fifth cause of action for a taking under the Fifth Amendment to the U.S. Constitution is brought in the alternative. Plaintiffs will pursue their fifth cause of action if and only if this Court fails to find in their favor on the first four causes.

[2] The "Final Rule," for purposes of this memorandum, means the "Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk, 69 Fed. Reg. 6788 (February 11, 2004). The Final Rule has an effective date of April 12, 2004.

[3] The Final Rule declares those dietary supplements adulterated under the FDCA § 402(f)(1)(A) (2004), 21 U.S.C. § 342(f)(1)(A), 69 Fed. Reg. at 6788.

[4] The manufacturing, holding, distributing, and sale of those dietary supplements are subject to criminal and civil penalties under 21 U.S.C. §§ 331(a), 332, 333(a), and 335b.

[5] Prior to the passage of DSHEA, dietary supplements were regulated under the FDCA as either foods or drugs. DSHEA created a separate regulatory structure for dietary supplements which are now treated as a subset of foods.

means that it presents "a significant or unreasonable risk of illness or injury." 21 U.S.C. § 343(f)(1)(A)(i), (ii). The FDA bears the burden of proof, and it must satisfy that burden by a preponderance of the evidence. Id. § 342(f)(1)(D). A reviewing court, such as this Court, "shall decide any issue under this paragraph on a de novo basis." Id. § 342(f).

The scientific and administrative record relied upon by FDA in support of the Final Rule fails to establish that dietary supplements containing 10 mg or less ephedrine alkaloids[6] per daily dose pose a "significant or unreasonable risk of illness or injury." 21 U.S.C. § 342(f). Lacking adequate scientific evidence to reach the end it desired – banning all dietary supplements containing any amount of ephedrine alkaloids – FDA adopted, for the first time, a "risk/benefit" analysis to determine whether dietary supplements containing ephedrine alkaloids present a "significant or unreasonable risk of injury or illness," the test required by DSHEA. FDA then applied this "risk/benefit" analysis to conclude in the Final Rule that, since it was unaware of evidence of *any* benefit to dietary supplements containing ephedra, *any* risk associated with the use of these products caused them to be adulterated under this newly adopted standard.[7] 69 Fed. Reg. at 6829.

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[6] Plaintiffs sold a whole-herb ephedra product (hereinafter "Low Dose Ephedra") comprised of 375 mgs of whole-herb ephedra powder per capsule. Whole-herb ephedra contains very low levels of ephedrine alkaloids–approximately 1%. Published references place the range between .75%-1% (see Merck Index, 2001) and 1.29% (see footnote 5 of Exhibit C). As with all natural products, actual content may vary based on harvest season and other factors. Plaintiffs have assumed a potency of 1% in its prior submissions to the FDA and for purposes of this motion.

[7] Even under a "risk/benefit" analysis, which Plaintiffs believe is illegal for reasons set forth in this motion, FDA exceeded its rulemaking authority because there is no evidence in the scientific or administrative record that dietary supplements with less than 10 mg per day of ephedrine alkaloids present any risk under ordinary conditions of use.

For the reasons set forth more fully herein, this Court should declare the Final Rule as promulgated by FDA void and remand the matter to FDA for rulemaking consistent with DSHEA and the FDCA. As demonstrated below, the Final Rule is void, first, because FDA did not satisfy its burden of proving that dietary supplements containing 10 mg or less ephedrine alkaloids per daily dose pose a "significant or unreasonable risk of illness or injury," as required by DSHEA, ignoring entirely the specific dose levels of Plaintiffs' Low Dose Ephedra, the warning statements contained on its labels, and the lack of scientific proof demonstrating any health risk in connection with Plaintiffs' Low Dose Ephedra.

Second, in contravention of the FDCA as amended by DSHEA, FDA in the Final Rule unilaterally modified and relaxed its own burden of proof. It accomplished this by adopting a new standard for the determination of whether any dietary supplement presents a "substantial or unreasonable risk of injury or illness," which is neither consistent with nor contemplated by the FDCA or DSHEA. Specifically, FDA concluded that it was authorized to impose its ban on the basis of *any* health risk based on a new "risk/benefit" test that it announced for the first time.

Third, FDA banned Plaintiffs' Low Dose Ephedra on the basis of supposed health risks associated with higher dose products rather than making a dose-specific determination based on the scientific and administrative record applicable to Plaintiffs' Low Dose Ephedra product.

Fourth, the FDA's Final Rule violates the FDCA and DSHEA by creating a regulatory scheme that is illogical in that it treats as adulterated dietary supplements with ephedrine alkaloids but allows the sale of food products containing the same active constituents at even

higher dose levels. Thus, the Final Rule is the product of FDA's compounded violations of the FDCA. Each violation, however, is independently sufficient to invalidate the Final Rule.

Separately and independently, the Final Rule is unlawful under the APA because it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" and "without observance of procedure required by law." 5 U.S.C.A. § 706(2)(A), (C), and (D). First, for the reasons summarized above and more fully set forth below, the Final Rule is arbitrary, capricious, and otherwise not in accordance with law. Second, in adopting the Final Rule, FDA failed to follow proper rulemaking procedure. Prior to the issuance of a rule that establishes a "standard of conduct" "having the force of law," FDA must provide notice of such proposed rule and an opportunity for public comment. 5 U.S.C. § 553(b)-(d). The Final Rule ushers in a new "risk/benefit" test to determine whether dietary supplements may be banned, but FDA failed to provide an adequate notice and comment period prior to adopting its new "risk/benefit" test. Either of these failures to comply with the APA is sufficient to invalidate the Final Rule.

For these reasons, the Court should: (1) declare the Final Rule invalid in violation of 21 U.S.C. § 342(f) and 5 U.S.C. §§ 553 and 706; (2) remand the matter to FDA for further rulemaking consistent with the Court's opinion; and (3) enjoin the Defendants from taking any enforcement action against Plaintiffs for their sale of a dietary supplement containing 10 mg or less of ephedrine alkaloids per daily dose.

STATEMENT OF UNCONTESTED MATERIAL FACTS

For the purposes of Plaintiffs' motion for summary judgment, pursuant to D.U.Civ.R. 56-1(b), Plaintiffs set forth the following material facts as to which no genuine issue exists and which entitle Plaintiffs to summary judgment.

1. The *Ephedra* genus of plants has been used as a tea for thousands of years. See e.g., Food and Drug Administration's (FDA's) Briefing Materials for Food Products Containing Ephedrine Alkaloids at 5 (October 11-12, 1995); 95N-0304, Vol. 39, Ref. 1.

2. *Ephedra* species include *Ephedra sinica* Staf, *Ephedra equisetina* Bunge, *Ephedra intermedia* var. tibetica Staf, and *Ephedra distachya* L. "Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk; Final Rule," 69 Fed. Reg. 6788, 6789 (February 11, 2004)(hereinafter "Final Rule"). Exhibit A.[8]

3. Naturally-occurring in some of the *Ephedra* genus of plants are the following: ephedrine, pseudoephedrine, norephedrine, methylephedrine, norpseudoephedrine, and methylpseudoephedrine (hereinafter collectively referred to as "ephedrine alkaloids"). Id.

4. The most predominant alkaloid in the *Ephedra* genus of plants is ephedrine. Id.

5. Since at least 1988, Solaray (purchased by Nutraceutical in 1993) has manufactured and sold a dietary supplement containing an ephedrine alkaloid (hereinafter "**Low Dose Ephedra.**") Exhibits B, C, D, and E.

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[8] Unless indicated otherwise, all exhibits referenced herein are attached to the Aff. of C. Hogle in Support of Plaintiffs' Motion for Summary Judgment.

6. **Low Dose Ephedra**, marketed at the time FDA's Final Rule was published, contains 375 mg of whole dried leaf *Ephedra sinica* per daily dose (which yields less than 10 mg of ephedrine alkaloids per daily dose). Exhibit B (label of **Low Dose Ephedra**) and E.

7. No other ephedrine alkaloid sources (and no synthetic ephedrine alkaloids) are added to Plaintiffs' **Low Dose Ephedra**. Id.

8. The label on Plaintiffs' **Low Dose Ephedra** recommends one capsule be taken no more than twice a day (yielding a total combined daily intake of ephedrine alkaloids of less than 10 mg per day). Id.

9. The label contains no marketing claims about the potential benefits or uses of the product. Id.

10. Nutraceutical produces no marketing materials that promote its **Low Dose Ephedra** product for any particular use or which make any claims about **Low Dose Ephedra**'s potential benefits. Exhibits B and E.

11. On June 4, 1997, FDA first published a notice of proposed rulemaking on dietary supplements containing ephedrine alkaloids (hereinafter "1997 Proposed Rule"). 62 Fed. Reg. 30678 (June 4, 1997), attached as Exhibit F. In it, Defendants proposed the following limitations on this class of products:

a. A dietary supplement would be adulterated and thus illegal to sell if it contained 8 mg or more of ephedrine alkaloids per serving or if its labeling recommended conditions of use resulting in an intake of 8 mg or more in a 6 hour period or a total daily intake of 24 mg or more;

b. The label on all dietary supplements containing ephedrine alkaloids would have to state that the product should not be used for more than seven days;

c. Dietary supplements containing ephedrine alkaloids could not be combined with certain other ingredients with a known stimulant effect;

d. The labeling for dietary supplements containing ephedrine alkaloids could not include claims for weight loss or body building that required long-term intake to achieve the purported effect;

e. The labeling for dietary supplements containing ephedrine alkaloids would have to include a warning that taking more than the recommended serving may result in serious adverse health effects. It must also warn to consult a health professional if the consumer has certain diseases and to stop use if he or she has certain signs or symptoms.

12. Plaintiffs filed comments on December 2, 1997, in response to the 1997 Proposed Rule, 62 Fed. Reg. 30678 (June 4, 1997). Exhibit G. Plaintiffs challenged the legal authority and evidentiary basis for FDA's proposed limitations on the sale of dietary supplements containing ephedrine alkaloids. Id.

13. On April 3, 2000, Defendants withdrew the following parts of the June 1997 proposal (hereinafter the "2000 Modification"):

a. That a supplement is adulterated if it contains 8 mg or more of ephedrine alkaloids per serving or if its labeling recommends conditions of use that would result in an intake of 8 mg or more in a 6 hour period or a total daily intake of 24 mg or more;

b. The analytical method for determining amounts present;

c. The label statement, "Do not use this product more than 7 days;"

d. The prohibition on labeling claims encouraging long-term intake;

e. The proposed warning for short term use.

65 Fed. Reg. 17474, attached as Exhibit H.

14. On March 5, 2003, the FDA published a notice in the Federal Register reopening the comment period for the 1997 proposed rule to consider a proposed warning statement. The notice also sought comment on whether, in light of information obtained since the 1997 rule, the FDA should find that dietary supplements containing ephedrine alkaloids present a "significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use." 68 Fed. Reg. 10417, attached as Exhibit I.

15. The March 5, 2003 notice in the Federal Register does not propose that supplements containing ephedrine alkaloids be analyzed using a "risk/benefit" analysis to determine whether they present a "significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling." Id.

16. Plaintiffs filed comments on April 7, 2003 in response to the March 5, 2003 notice. See Exhibit C. Plaintiffs requested that their product, **Low Dose Ephedra**, be excepted from any final rule adopted by FDA because of its low levels of ephedrine alkaloids, the lack of scientific evidence of serious risk associated with its low levels, and the absence of serious adverse events associated with it. Id.

17. Plaintiffs submitted additional comments on January 30, 2004, again requesting an exception. See Exhibit D. Defendants did not respond to that request.

18. On February 11, 2004, the FDA published the Final Rule (effective April 12, 2003) banning all ephedrine alkaloid containing dietary supplements including Plaintiffs' **Low Dose Ephedra**, doing so without regard to the amount of ephedrine alkaloids present and regardless of whether the ephedrine alkaloid content was naturally occurring or an extract having artificially elevated potency. 69 Fed. Reg. 6788; Exhibit A.

19. In FDA's Final Rule, FDA did not address Plaintiffs' comments, and, so, on April 20, 2004, Plaintiffs for the fourth time requested that FDA except Plaintiffs' **Low Dose Ephedra** product from the Final Rule. Plaintiffs submitted additional proof that their dietary supplement containing low levels of ephedrine alkaloids was not associated with any serious adverse event and contained ephedrine levels not known to produce any significant adverse effects. See, Exhibit J. Defendants did not respond to the request.

20. FDA has no scientific evidence from well-designed human clinical trials establishing that ephedrine alkaloids of 10 mg or less per day cause any significant adverse effect. See, id. at 3, 5, and 6.

21. The daily consumption of 10 mg or less of ephedrine alkaloids is not associated with acute or cumulative adverse effects on the cardiovascular system. Id. at 7.

22. The Final Rule is the first time FDA has banned an entire class of dietary ingredients from being sold in the U.S. See, "Remarks by Lester M. Crawford, DVM, Ph.D.,

Acting Commissioner of FDA for Public Affairs Workshop" (April 19, 2004) at http://www.fda.gov/oc/speeches/2004/aspet0419.html., attached as Exhibit K.

23. The Final Rule is the first time FDA has invoked section 21 U.S.C. § 342(f)(1)(A) as its statutory authority to find a dietary supplement or ingredient adulterated. See, 69 Fed. Reg. at 6794; see also, "Dietary Supplements Containing Ephedrine Alkaloids Final Rule Summary" at http://www.fda.gov/oc/initiatives/ephedra/february2004/finalsummary.html, attached as Exhibit L.

24. The Final Rule is the first time FDA has proposed a "risk/benefit" analysis as a standard for determining whether a dietary supplement presents a "substantial or unreasonable risk of injury or illness."

ARGUMENT

Under Fed. R. Civ. P. 56(c), summary judgment shall be granted "if ... there is no genuine issue as to any material fact and . . . the moving party is entitled to judgment as a matter of law." United States v. Denver, 100 F.3d 1509, 1512 (10th Cir. 1996). A factual dispute is "genuine" if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. Kaul v. Stephan, 83 F.3d 1208, 1212 (10th Cir. 1996). A fact is "material" if it might affect the outcome of the suit under the governing substantive law. Id.

I. PLAINTIFFS ARE ENTITLED TO SUMMARY JUDGMENT ON CLAIMS 1 THROUGH 4 OF THEIR COMPLAINT.

In this case, the Court should enter summary judgment in Plaintiffs' favor because there is no genuine issue of material fact and Plaintiffs are entitled to judgment as a matter of law that the Final Rule is void because FDA failed to satisfy its burden of proof relative to dietary supplements containing 10 mg or less ephedrine alkaloids per daily dose and because the Final Rule is unlawful under the APA.

A. The Final Rule Is Void Because FDA Did Not Satisfy Its Burden Of Proving That Dietary Supplements Containing 10 mg Or Less Ephedrine Alkaloids Per Daily Dose Pose A Significant Or Unreasonable Risk Of Illness Or Injury.

1. The FDCA's Application And Regulation Of Dietary Supplements.

At the center of this challenge is the DSHEA, which is incorporated into the FDCA. In 1994, Congress passed the DSHEA, which authorizes FDA to prohibit the sale of dietary supplements that present a "significant or unreasonable risk of illness or injury under conditions of use . . . recommended or suggested in labeling." 21 U.S.C. § 342(f)(1)(A). The DSHEA is

unusual in that Congress specified that "[t]he court shall decide any issue under this paragraph on a de novo basis." Id. § 342(f)(1)(D). That section, therefore, exempts FDA bans of dietary supplements from the general rule that agency interpretations of its statutory authority are entitled to deference.[9]

Under the FDCA, a dietary supplement is to be regulated as if it were a food. 21 U.S.C. § 321(ff). Like a food, a dietary supplement may not be banned unless and until FDA proves, by a preponderance of the evidence, that, at the dosage indicated in labeling, it poses a "serious or unreasonable risk of illness or injury under conditions of use . . . recommended or suggested in labeling." 21 U.S.C. § 343(f)(1)(A)(i), (ii). Because FDA never satisfied its burden of proof to hold **Low Dose Ephedra**, adulterated, its Final Rule banning that supplement is unlawful.

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[9] Even under the general rule governing agency statutory construction, Chevron USA, Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984); see also, U.S. v. Mead Corp., 533 U.S. 218 (2001)), the Court must determine whether Congress has spoken to the precise question at issue, and if it has, then the analysis ends and Congress' clear intent controls. Chevron at 842; see also, FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000); Pharmanex v. Shalala, 221 F.3d 1151, 1154-54 (10th Cir. 2000). "In a statutory construction case, the beginning point must be the language of the statute, and when the statute speaks with clarity to an issue[,] judicial inquiry into the statute's meaning, in all but the most extraordinary circumstance, is finished." Estate of Cowart v. Nicklos Drilling Co., 505 U.S. 469, 475 (1992) (citing Demarest v. Manspeaker, 498 U.S. 184, 190 (1991)). "In ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole." K Mart Corp. v. Cartier, Inc., 486 U.S. 281, 291 (1988). If the statute is silent or ambiguous as to the specific issue, then the Court must defer to the agency interpretation if it is based on a permissible construction. Chevron, 467 U.S. at 843.

Under the general rule, agency interpretations must be reasonable; if they are arbitrary, capricious, or manifestly contrary to the statute, they are not entitled to deference. Pharmanex, 221 F.3d at 1154 (citing Chevron at 844). In purely legal questions of statutory interpretation, a "realm of judicial expertise, the courts, not the agency, have the last word." U.S. v. 29 Cartons of...an article of food [Oakmont Investment Co.], 987 F.2d 33 (1st Cir. 1993) (citing Chevron at 843 n.9; BATF v. FLRA, 464 U.S. 89, 98 (1983) (observing that "deciding what a statute means" is "the quintessential judicial function") (citations omitted)). "The simple fact that the agency has a position, in and of itself, is of only marginal significance." 29 Cartons, 987 F.2d at 38 (citing Mayburg v. Secretary of HHS, 740 F.2d 100, 106 (1st Cir. 1984)). "When, as now, a court is persuaded neither by 'the validity of [the agency's] reasoning,' nor by the interpretive fit between the agency's rendition, on [the] one hand, and the language and structure of the statute, on the other hand, a court should not defer." 29 Cartons, 987 F.2d at 38-39 (citing Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)).

The treatment of dietary supplements as foods is mandated by the FDCA. The FDCA's definition of a dietary supplement, 21 U.S.C. § 321(ff), states in part: "Except for purposes of section 201(g) [the definition of a drug], a dietary supplement shall be deemed to be a food within the meaning of this Act." Also, the FDCA's dietary supplement safety provision is within the adulteration section for foods: section 402 (21 U.S.C. § 342).[10] Thus, under the plain language of the FDCA, dietary supplements are to be regulated as if they were foods.

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[10] That section reads, in part:

A food shall be deemed to be adulterated –

* * *

(f) -

(1) If it is a dietary supplement or contains a dietary ingredient that –

(A) Presents a significant or unreasonable risk of illness or injury under –

(i) conditions of use recommended or suggested in labeling, or

(ii if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;

(B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;

(C) the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5, United States Code, to affirm or withdraw the declaration; or

(D) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.

In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide any issue under this paragraph on a de novo basis.

(2) Before the Secretary may report to a United States attorney a violation of paragraph (1)(A) for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before such notice, with regard to such proceeding.

21 U.S.C. § 342(f)(emphasis added).

The FDCA's legislative history underlying 21 U.S.C. § 342(f) likewise makes clear that dietary supplements and foods should be regulated in the same way. Legislative history must be consulted in the construction of statutes. See, e.g., Pharmanex v. Shalala, 221 F.3d 1151, 1158 (10th Cir. 2000) (considering legislative history for DSHEA in a statutory construction analysis of 21 U.S.C. § 321(ff)(3)(B)).

The Senate Report for DSHEA describes how FDA should apply the standard for dietary supplements:

> [S]ection 4 provides new power to the FDA to declare a dietary supplement adulterated through rulemaking. FDA may use this power where it is determined that a dietary supplement presents a "substantial and unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling." In such an instance, the FDA would publish a notice in the Federal Register proposing to declare a dietary supplement adulterated and setting forth the basis for [the] position that a substantial and unreasonable risk of illness or injury is presented. **In so doing, the FDA would be required to describe in the notice how such risks are presented under "the conditions of use recommended or suggested in labeling."** FDA would thus be required to consider whether certain conditions of use would not present a substantial and unreasonable risk of illness or injury. After receiving comments on such a proposal the FDA could then establish by regulation that a dietary supplement would be adulterated if it contained an ingredient at all or at levels which present a substantial or unreasonable risk.

S. REP. 10-410 at 35 (emphasis added).

Dietary supplements, like foods, may be sold in the United States without obtaining FDA's pre-market approval, and they are saleable so long as they do not threaten public health at the level of daily servings or doses recommended in their labeling. 21 U.S.C. § 342(a)(foods may not be sold if they contain constituent ingredients that "may render [them] injurious to health" unless the "quantity of such substance in such food does not ordinarily render it injurious

to health"); 21 U.S.C. § 342(f)(1)(A)(supplements may not be sold if they contain dietary ingredients that "presents a significant or unreasonable risk of illness or injury under …conditions of use recommended or suggested in labeling…").

2. Before Dietary Supplements May Be Banned, The FDA Must Prove That The Dietary Supplements Pose A Significant And Unreasonable Health Risk And Do So At The Dose Levels Indicated On The Dietary Supplement Label.

FDA has the burden of proof, and not only must FDA prove that dietary supplements pose a significant or unreasonable health risk, but it must also prove that they pose such a risk at the dose levels indicated in labels. 21 U.S.C. § 342(f). In equating dietary supplements to foods for regulatory purposes, Congress made the safety determination necessarily dose specific, i.e., "under the conditions of use recommended or suggested on the label or the labeling of such dietary supplement." 21 U.S.C. § 342(f)(1)(A). If a dietary supplement was safe at some dose levels for the general population (or unsafe at certain dose levels for a population subgroup), labeling change would ordinarily be warranted: "products may be labeled so that certain subgroups of the population may be advised that a dietary supplement is not safe for their use." S. REP., supra, at 36. **"In addition, a safety finding cannot be entered against a supplement based upon a dosage not recommended to consumers in the labeling."** Id. (emphasis added). "[T]he government's interest in preventing the use of labels that are true but do not mention adverse effects would seem to be satisfied – at least ordinarily – by inclusion of a prominent disclaimer setting forth those adverse effects." Pearson v. Shalala, 164 F.3d 650, 659 (D.C. Cir. 1998).

Where a dietary supplement has directions for use or conditions for use, the Senate report states, "the dietary supplement would not be deemed adulterated unless it 'may be' injurious or 'ordinarily' injurious to the population **under the warnings and directions and conditions of use recommended in the labeling**." S. REP. NO. 103-410 at 36. (emphasis added). As Congress intended it, a ban on an entire dietary supplement would be permitted only if the supplement were proven to present a significant or unreasonable risk of illness or injury at every dose level in light of actual product labeling. Thus, under its burden of proof, FDA cannot – as it has done in the Final Rule – ban a dietary supplement outright without proof by a preponderance of the evidence that it presents a significant or unreasonable risk of illness or injury at every dose level.

Where FDA has previously sought to declare a food adulterated without a preponderance of the evidence, the courts have held it not to have met its statutory burden. See e.g., U.S. v. 55 Cases Popped Corn, 62 F. Supp. 843, 844-45 (D. Id. 1943)(because there is no evidence to support the facts alleged, there is no proof and "the popped corn could not be found to be adulterated within the meaning of the statute"); U.S. v. 1232 Cases American Beauty Brand Oysters, 43 F. Supp. 749 (W.D. Mo. 1942)("On the contrary, a preponderance of the evidence showed that the [manufacturer's] processing methods were superior"); see also, Millet, Pit and Seed Co., Inc. v. U.S., 436 F. Supp. 84, 88 (E.D. Tn. 1977); U.S. v. One Can of Kololiva; 24 F. Supp. 110 (D. Mass. 1938)(applying the Food and Drug Act which predated the FDCA)(lead present in oil was found to be so small as not to render the food adulterated).

3. FDA, In Its Final Rule, Wholly Failed To Meet Its Burden In Banning Dietary Supplements Containing 10 mg Or Less Ephedrine Alkaloids Per Daily Dose.

FDA found no clinical trial evidence proving significant or unreasonable risk of illness or injury at the 10 mg or less level. C.F., 69 Fed. Reg. at 6829. Despite the absence of needed evidence, FDA banned even low dose ephedrine alkaloid containing dietary supplements, on the basis that it was "not aware of any evidence that establishes a safe dose of ephedrine alkaloids in dietary supplements." 69 Fed. Reg. at 6829. Ignorance of evidence is not the same as a preponderance of the evidence proving significant or unreasonable risk of illness or injury. FDA did not satisfy its burden of proof when it accepted no evidence as proof of adulteration. See, S. REP. NO. 103-410 at 36 ("The government must produce the preponderance of evidence as to harmful effects from the dietary supplement when used as recommended and suggested in the labeling") (citing U.S. v. 71/55 Gallon Drums of Stuffed Green Olives, 790 F. Supp. 1379 (N.D. Ill. 1992)); see also, e.g., U.S. v. International Exterminator Corp., 294 F.2d 270 (5th Cir. 1961); Golden Grain Macaroni Co. v. U.S., 209 F.2d 166 (9th Cir. 1953).

Nowhere in the Final Rule do Defendants acknowledge that they must satisfy the preponderance of the evidence standard. See id. Instead, FDA states that "**any** science-based evidence" is sufficient to support a finding of adulteration based on its new risk/benefit test. Id. at 6798 and 6822 (emphasis added). Not so, FDA needs a preponderance of the science-based evidence to meet its burden.

Thus, FDA chose to condemn ephedrine at low dose levels, not because it possessed clinical trial proof that those levels present a significant or unreasonable risk of illness or injury, but because FDA was "unaware" of whether such risk existed. 69 Fed. Reg. at 6829. FDA failed to satisfy its burden of proof.

4. FDA Bypassed The Evidentiary Requirements For Banning A Dietary Supplement By Unilaterally Lowering Its Hurdles In Violation Of The FDCA.

Instead of satisfying the burden of proof directed by the FDCA, FDA unilaterally relaxed its burden in at least four respects. First, FDA suggested that it need only have evidence that supports the existence of any health risk rather than a "significant or unreasonable" health risk. Second, contrary to the FDCA, 21 U.S.C. § 342(f), FDA used a new "risk/benefit" test supported nowhere in the FDCA, demanding proof of a significant "benefit" to offset any risk as a condition precedent to saleability. Third, FDA purported to ban dietary supplements containing low doses of ephedrine alkaloids on the basis of supposed health risks posed by supplements with higher doses. Fourth, FDA treated dietary supplements differently from foods under 21 U.S.C. § 342(f)(1)(A), contrary to the FDCA and the DSHEA.

(i) FDA disregarded its burden of proving, by a preponderance of the evidence, that dietary supplements containing ephedrine alkaloids pose a "significant or unreasonable risk" of illness or injury. In its Final Rule, FDA proposed that it only need "scientific evidence that **supports the existence** of risk." Id. (emphasis added). To the contrary, while no actual injury to the public need be shown, the agency must **prove** significant or unreasonable risk of illness or injury by a preponderance of the evidence. Pine Street Trading Corp v. Farrell Lines, Inc., 364

A.2d 1103 (Ct. App. Md. 1976) (citing U.S. v. International Exterminator Corp., 294 F.2d 270 (5th Cir. 1961); Golden Grain Macaroni Co. v. U.S., 209 F.2d 166 (9th Cir. 1953); U.S. v. 1,200 Cans, Pasteurized Whole Eggs, 339 F. Supp. 131, 141 (N.D. Ga. 1972)). Adulteration under 21 U.S.C. § 342(f)(1)(A) is not the existence of any risk but "a significant or unreasonable risk" by a preponderance of the evidence.

(ii) FDA's new risk/benefit test seriously understates and shifts FDA's burden under the FDCA. In the Final Rule, FDA creates a new test for determining whether a dietary supplement presents a significant or unreasonable risk of illness or injury. 69 Fed. Reg. at 6794. FDA finds any risk of injury or illness to constitute adulteration unless the dietary supplement in question is shown to provide a significant benefit. 69 Fed. Reg. at 6798, 6799, 6825-6827. FDA's risk/benefit test demands that a supplement produce a significant benefit to offset even the slightest evidence of risk. See, 69 Fed. Reg. at 6788 ("...in the absence of a sufficient benefit, the presence of even a relatively small risk of an important adverse health effect to a user may be unreasonable"). That "risk/benefit" test does not follow the preponderance of the evidence and "significant or reasonable" health risk standard of the FDCA. Indeed, it conflicts with the FDCA as a whole.

The FDCA does not require proof of benefit before a food or a dietary supplement is legally saleable. Congress created a distinct "dietary supplement" regulatory category in the DSHEA, codified at 21 U.S.C. § 321(ff). In defining what constituted a dietary supplement, Congress specified the kinds of ingredients, mode of ingestion, and form of delivery vehicle, but not any need for proof of a "benefit," as condition precedents to dietary supplement status or

saleability. See id. In the DSHEA, Congress also recognized as not adulterated, i.e., as lawfully saleable, every dietary ingredient marketed in the United States before the effective date of the DSHEA, i.e., before October 14, 1994. 21 U.S.C. §§ 331(v) and 350b(c). Again, it did so without requiring any proof of benefit as a condition precedent to saleability.

Indeed, Congress' dissatisfaction with FDA's attempts to require such proof was one of the very reasons the DSHEA was enacted. Prior to the DSHEA, FDA treated dietary *supplements as food additives rather than as foods, which erroneously put the burden of proof for* safety on the dietary supplement manufacturer rather than on FDA. See U.S. v. 29 Cartons [Oakmont Investment Co.], 987 F.2d 33 (1st Cir. 1993). U.S. v. Two Plastic Drums, more or less..., 984 F.2d 814 (7th Cir. 1993). That practice was squarely condemned by Congress in enacting the DSHEA:

> In the committee's judgment, the FDA has disregarded the congressional intent underlying the law regulating food and food additives. That law plainly declares that a food may be sold unless the FDA finds that it is "injurious to health." In the absence of such evidence, the FDA has attempted to twist the statute in what the Committee sees as **a result-oriented effort to impede the manufacture and sale of dietary supplements**. *We believe these "enforcement" actions discredit the agency and bring the law into* disrepute, and has led to harassment and hardship for companies forced to defend themselves against this inappropriate regulatory strategy.
>
> The Committee's amendment will correct this abuse by **rationalizing** the treatment of dietary supplements **according to the pattern of the existing statute**, and in conformity with the original congressional intent.

S. REP. 103-410 at 22 (emphasis added).

If Congress had wished to impose a requirement that dietary supplements provide a demonstrable benefit before entering the market, imposing this requirement on new dietary

ingredients would have been not only logical but imperative. Not imposing the requirement on new dietary ingredients supports the view that Congress did not intend to impose such a requirement on dietary supplements of any kind. Thus, the Final Rule's "risk/benefit" test (with its requirement that dietary supplements be proven to produce a significant benefit if shown to produce any risk) redefines the FDCA's requirements for dietary supplements by compelling proof of benefit when the Act (as written and as intended) requires no such proof.

Food safety determinations, which under the FDCA are applicable to dietary supplements, do not include a weighing of a food's benefit. See, 21 U.S.C. § 342. The language of section 342(a)(1), the most analogous section for banning a food substance based on risk of illness or injury, states that a food shall be deemed adulterated "if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health." Id. The remaining subsections of the food adulteration section make no mention of an assessment or weighing of a food's benefit. See 21 U.S.C. § 342. Thus, the plain language of the food adulteration section does not support FDA's demand for proof of a benefit. Should the adulteration test created in the Final Rule stand, FDA will be given judicial license to treat dietary supplements and foods disparately.[11] In so doing, FDA would be acting directly contrary

[11] If food manufacturers were required to show "benefit" to outweigh any risk, that would likely mean that potato chips, ice cream, candy and the like be deemed, adulterated. Dietary supplements are, by and large, dietary ingredients (a subset of foods). For example, Plaintiffs **Low Dose Ephedra** is the same herbal substance as the ephedra in ephedra tea.

to Congress's clearly expressed intent that the DSHEA harmonize the regulatory treatment of supplements with that of foods. 21 U.S.C. § 321(ff) and S. REP. 103-410 at 22.

FDA's assertion that the statutory term "unreasonable" in subsection 342(f)(1)(A) "connotes comparison of the risks and benefits of the product" is an erroneous assumption, void of any basis in the statute or in the legislative history. 69 Fed. Reg. at 6823. The language of section 342(f)(1)(A) makes no use of the term "benefit" or any word that could reasonably be construed as requiring a "benefit." The section focuses solely on the existence of risk, not just any risk but a "significant or unreasonable risk of illness or injury."[12] Compare 21 U.S.C. § 321(f) and 321(ff) and 342(f)(1)(A). The phrase "unreasonable risk" is thus appropriately evaluated without any examination of benefit. Simply stated, a low level of risk (one that does not cause significant illness or injury) is reasonable, and a high level of risk (one that does cause such illness or injury) is unreasonable. Furthermore, FDA's interpretation conflicts with the legislative intent to regulate dietary supplements and foods alike. Thus, FDA's construction materially and fundamentally deviates from the statutory scheme for dietary supplements prescribed by the Act and intended by Congress.

FDA's citation to the medical device classification provisions of the FDCA to support its risk-benefit interpretation of "unreasonable" risk is entirely misplaced. In the medical device statutory language, Congress has specifically directed that the agency weigh the benefits to health

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[12] In FDA's assessment, the term "significant" is a dead letter, 21 U.S.C. § 342(f)(1)(A), as if it did not exist in the statute and does not modify the term "risk." That FDA decision to give a statutory term no meaning violates the canons of statutory construction. See, Legal Environmental Assistance Foundation, Inc. v. EPA, 118 F.3d 1467 (11th Cir. 1997)("[w]e do not start form the premise that [the statutory] language is imprecise. Instead we assume that in drafting legislation, Congress said what it meant")(citations omitted).

against the risk of illness or injury. 21 U.S.C. § 360c(a)(2)(C)("the safety and effectiveness of a device are to be determined...weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such issue"). That test makes sense for medical devices because a medical device, unlike a food or a dietary supplement, is an intervention to cure, treat, mitigate or prevent a disease. See 21 U.S.C. § 321(h)(2). A medical device must produce a curative benefit to be efficacious. See 21 U.S.C. § 513(a)(1). Foods and dietary ingredients are not required to produce a benefit.

Thus, FDA's adoption of a "risk/benefit test" conflicts with the statute as a whole. It redefines "dietary supplement" in 21 U.S.C. § 321(ff) by effectively requiring proof of a benefit as a condition precedent to saleability. It, in pertinent part, makes the new dietary ingredient provision in 21 U.S.C. § 350b, which does not require proof of benefit, nonsensical and a logical absurdity. Finally, it conflicts with the adulteration test for foods, destroying the harmony intended by the DSHEA. FDA has deviated from its statutory strictures and erroneously created a test for adulteration based on two characteristics, risk and benefit, although benefit is not a characteristic that is statutorily required (or logically applicable) to a food or dietary supplement.

(iii) FDA improperly eased its burden by failing to account for dietary supplements containing ephedrine alkaloids at low dose levels. Another of FDA's departures from the FDCA is its decision to ban dietary supplements with low levels of ephedrine alkaloids on the basis of health risks posed by such supplements with high levels of ephedrine alkaloids. The plain language of 21 U.S.C. § 342(f)(1)(A) does not authorize FDA to ban a supplement with amounts of an allegedly harmful ingredient without proof that the amounts contained within the

supplement present a significant or unreasonable risk of illness or injury. Nor does Section(f)(1)(A) authorize FDA to conclude that a probable risk at some dose level supports a ban at all dose levels. 21 U.S.C. § 342(f) plainly places the burden of proof on FDA, by a preponderance of the evidence, to show that a dietary ingredient presents a substantial or unreasonable risk of illness or injury. FDA utterly failed to satisfy that burden for dietary supplements containing 10 mg of ephedrine alkaloids or less per daily dose.[13]

All ingestible substances will, at some level of ingestion, produce harm (even water). See e.g., John N. Hathcock, Nutritional Toxicology 2-3 (1982); Cf. U.S. v. Lexington Mill Co., 232 U.S. 399, 412 (1914) ("As to the term 'poisonous,' let me state that everything which contains poison is not poison. It depends on the quantity and the combination. A very large majority of the things consumed by the human family contain, under analysis, some kind of poison, but it depends upon the combination, the chemical regulation which it bears to the body in which it exists as to whether or not it is dangerous to take into the human system" (quoting a Congressional sponsor of the original Food and Drugs Act of 1906)); see also, Millet, Pit and Seed Co., Inc. v. U.S., 436 F. Supp. 84, 88 (E.D. Tn. 1977). A universal principle of that kind cannot serve to distinguish dietary ingredients with an unreasonable risk of illness or injury from those without that risk. Under 342(f)(1)(D), a dietary ingredient is not adulterated if the quantity of the substance in a food does not ordinarily render the dietary ingredient injurious to health under the conditions of use recommended or suggested in the labeling of the dietary supplement.

[13] In the Final Rule, FDA argues that a complete ban is more efficient than a case by case determination. 69 Fed. Reg. at 6830. That may be so from FDA's vantage point, but FDA's indelicate choice of a total ban in this case does not satisfy the agency's burden of proof under 21 U.S.C. § 342(f).

Thus, a rational distinguishing principle only arises when a dose-specific evaluation is employed, something the Final Rule failed to do. FDA's irrational interpretation of the statute cannot sustain its regulation.[14] See, Reinkraut, 854 F. Supp. at 844 (citing Chemical Mfrs. Assn. v. Natural Resources Defense Council, Inc., 470 U.S. 116, 125 (1985)).

FDA's interpretation is entitled to no deference because the statutory section in issue requires de novo review. 21 U.S.C. § 342(f). Moreover, even if deference were an option, it should not be given because FDA's statutory interpretation is at odds with the Congressional intent. Chevron, 467 U.S. at 845 (citing U.S. v. Shimer, 367 U.S. 374, 382-383 (1961)). "An administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress." Brown & Williamson Tobacco, 529 U.S. at 161. In Pactra Industries, Inc. v. CPSC, 555 F.2d 677 (9th Cir. 1977), the Ninth Circuit overturned a CPSC regulation banning as a hazardous substance all self-pressurized products containing a vinyl chloride monomer because the CPSC did not follow the procedures mandated by the FDCA section 701(e), 21 U.S.C. § 371(e). See, 555 F.2d at 684. The Ninth Circuit found that Congress

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[14] Indeed, were it the case that a risk at some dose level would support a complete ban, then no dietary supplement could survive a safety review. For example, selenium, a widely sold and important antioxidant mineral for which FDA has allowed a health claim (U.S. Food and Drug Administration, *Summary of Qualified Health Claims Permitted*, CFSAN/Office of Nutritional Products, Labeling, and Dietary Supplements, *at* http://www.cfsan.fda.gov/~dms/qhc-sum.html#selenium (Sept. 2003)) is toxic in minute doses, i.e., any daily dose above 1 mg produces neurological disorders. See Sheldon Saul Hendler & David Rorvik, Physician's Desk Reference for Nutritional Supplements 420 (1st ed. 2001). Were the adulteration test in the Final Rule applied, selenium could be banned from the market even in safe daily dose levels below 0.4 mg. Vitamin C at dose levels above 3 grams per day can cause diarrhea which could severely debilitate or injure those with compromised immune systems. Id. at 420. Using FDA's new "risk/benefit" rule, Vitamin C could also be banned. Indeed, virtually every dietary supplement could be banned because at some dose level every one can be toxic, as is true of foods generally. See, MacReady, N., "Endurance Athletes at Risk of Water Intoxication," http://my.webmd.com/content/article/36/1676_50497.htm? lastselectedguid={5FE84E90-BC77-4056-A91C-9531713CA348}.

had dictated a certain procedure and method of fact-finding for such a regulation, and the agency did not follow it. See, id. at 684-685 ("The procedural prerequisites to rule making...serve to impose a discipline on the agency's decision-making process, forcing it to present ordered proof to support its position").

Congress was clearly concerned that an adulteration examination depend on proof of actual use and dosing reflected in product labeling. S. REP. NO. 103-410 at 35 ("FDA would thus be required to consider whether certain conditions of use would not present a substantial and unreasonable risk of illness or injury"); id. at 36 ("[a] safety finding cannot be entered against a supplement based upon a dosage not recommended to consumers in the labeling"). "In our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." U.S. v. Article of Drug...Bacto-Unidisk, 394 U.S. 784, 800 (1969)(citing 62 Cases of Jam v. U.S., 340 U.S. 593 (1951)). Congress specifically dictated an enforcement process in which "FDA would thus be required to consider whether certain conditions of use would not present a substantial and unreasonable risk of illness or injury." S. REP. NO. 103-410 at 35. Clearly FDA is charged with determining those levels at which there is, and below which there is not, a significant or unreasonable risk. That it did not do in the Final Rule.

(iv) The Final Rule treats foods containing ephedrine alkaloids differently from dietary supplements with the same ingredient. Although ephedrine alkaloids exist in foods, such as teas, FDA states that the Final Rule does not apply to ephedrine alkaloids in conventional foods. 69 Fed. Reg. at 6793. That distinction reflects a fundamental departure from the FDCA's mandate

that foods be regulated similarly to dietary supplements. The FDCA's definition of a dietary supplement states, in pertinent part, "[e]xcept for purposes of section 201(g)[the definition of a drug], a dietary supplement shall be deemed to be a food within the meaning of this Act." 21 U.S.C. § 321(ff). Congress intended the DSHEA to "rationaliz[e] the treatment of dietary supplements according to the pattern of the existing statute [i.e., for foods]." Sen. Rep. 103-410 at 22. S. REP. NO. 103-410 (1994). Moreover, Congress intended the DSHEA to rectify FDA's past effort "to impede the manufacture and sale of dietary supplements." Id. at 22. Clearly, Congress did not intend to create a regime that would cause the very same substance and quantity of a dietary ingredient to be lawful as a food but unlawful as a dietary supplement. Id. That kind of illogical action by FDA, at odds with its own governing statute, has been soundly condemned by the federal courts. See, 29 Cartons, 987 F.2d at 37-38; see also, U.S. v. Two Plastic Drums, more or less..., 984 F.2d 814 (7th Cir. 1993). Thus, the Final Rule's disparate treatment of ephedrine alkaloids in conventional foods and dietary supplements violates the FDCA. FDA's creation of disparate adulteration standards for foods and dietary supplements in the Final Rule offends that harmonious union intended by Congress and reflected in Section 321(ff).

Not only does the Final Rule conflict with the FDCA as a whole, but its disparate treatment of foods and dietary supplements places an irrational, incongruous, and unworkable construction upon the Act. As FDA has it, herbal ephedra in a tea or other food is legal. FDA's position is profoundly illogical. FDA cannot be taken seriously when it contends that ephedrine alkaloids in dietary supplements are adulterated at every dose level when it also holds those same alkaloids lawfully saleable in any dose level when naturally occurring in foods.

5. Summary.

In sum, the Final Rule is contrary to the FDCA. FDA did not satisfy its burden of proving, by a preponderance of the evidence, that dietary supplements containing 10 mg or less ephedrine alkaloids per daily serving presented a significant or unreasonable risk of illness or injury. Indeed, FDA practically admitted that it could not do so. Such admission is manifested in FDA's attempt to ease its burden of proof, in conflict with the FDCA. First, recognizing that it could not satisfy its burden of proving a "significant or unreasonable" risk, FDA suggested that it could ban dietary supplements on the basis of any risk. Second, unable to satisfy the FDCA's standard for a ban of dietary supplements, FDA invented a standard–its "risk/benefit" analysis–that it could satisfy. Third, recognizing its inability to demonstrate significant or unreasonable health risks of dietary supplements with low levels of ephedrine alkaloids, FDA suggested that dietary supplements with any level of such ingredient may be treated alike. Fourth, having decided not to ban foods with ephedrine alkaloids, FDA separated dietary supplements containing the same substance and treated them differently than foods, in violation of the FDCA as a whole. For these reasons, the Final Rule is invalid as to dietary supplements containing 10 mg or less ephedrine alkaloids per daily serving.

B. The Final Rule Is Unlawful Under The APA.

Under the APA, agency rules are "unlawful," and hence void, if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). For reasons similar to those presented above, the Final Rule is not in accordance with law and is arbitrary and capricious. In addition, the Final Rule is unlawful under the APA

because it adopts a "risk/benefit" test without giving proper notice and opportunity for public comment.

1. FDA's Failure To Except From Its Ban Dietary Supplements Containing 10 mg Or Less Ephedrine Alkaloids Per Daily Dose Is Arbitrary And Capricious.

Whether an agency acted in an arbitrary and capricious manner is determined by whether the agency's decision was based on a consideration of the relevant factors and whether it has made a clear error of judgment. Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971). An agency decision will be considered arbitrary and capricious if "the agency relied on factors **which Congress had not intended it to consider**, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Motor Vehicles Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29, 43 (1983)(emphasis added); see also, Humana of Aurora v. Heckler, 753 F.2d 1579, 1581 (10th Cir. 1985)(citations omitted). "A rational connection must be found between the facts before the agency and the rule-making choice made." Id. (citing Motor Vehicle Mfrs., 463 U.S. 29; see also, Burlington Truck Lines v. U.S., 371 U.S. 156, 168 (1962).

As discussed above, the agency's ban on dietary supplements containing 10 mg or less ephedrine alkaloids per daily dose is irrational and unreasonable. That ban is not backed by the preponderance of scientific evidence. See 69 Fed. Reg. at 6829. The test yielding that result is not authorized by the FDCA. FDA's assumption of power is an extrastatutory reach previously rejected by the U.S. Supreme Court when applied to foods. Compare 69 Fed. Reg. at 6829 and

6796 with Lexington Mill Co., 232 U.S. at 412. FDA's ban is based on a deliberate disregard of a congressional directive (in both the statutory language and legislative history of DSHEA). 21 U.S.C. § 342(f)(1)(A)(i); S. REP. NO. 103-410 at 35 and 36. Thus, the agency has relied on factors that Congress did not intend for it to consider. See, Motor Vehicles Mfrs. Ass'n, 463 U.S. at 43. There is no rational connection between the facts before the agency, the standards of the FDCA, and FDA's determination to ban Plaintiffs' low dose ephedrine alkaloid containing dietary supplements. Thus, the Final Rule is arbitrary and capricious agency action in violation of the APA. 5 U.S.C. § 706(2)(A).

2. FDA's Incongruous Treatment Of Herbal Ephedra In Food Form And In Supplement Form Is Arbitrary And Capricious.

FDA's public health law and policy lacks rationality when an ingredient in a dietary supplement is banned as adulterated but the very same ingredient in the same quantity is lawfully saleable as a food. There is no logic or rationality in treating the same substance differently solely because it is encapsulated and sold as a dietary supplement rather than placed in a tea bag and sold as a food. See, Hurley v. U.S., 575 F.2d 792 (10th Cir. 1978). Congress intended the agency to treat foods and dietary supplements harmoniously. The Final Rule flouts that intention, erecting an incongruous, irrational and unworkable scheme in its place. 21 U.S.C. 321(ff); 21 U.S.C. 342; compare 21 U.S.C. § 342(a)(1) and 21 U.S.C. § 342(f)(1)(D). The Final Rule is thus arbitrary and capricious agency action, an abuse of discretion, and otherwise not in accordance with law. 5 U.S.C. § 706(2)(A).

3. FDA Violated The APA's Rulemaking Requirements By Adopting A Risk/Benefit Test Without Notice And Comment.

In the Final Rule, FDA applied, for the first time, a risk/benefit test to determine if dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury. 69 Fed. Reg. at 6794 ("We are using this rulemaking authority for dietary supplements containing ephedrine alkaloids because we are articulating a standard for unreasonable risk under 402(f)(1)(A) of the act for the first time..."). Prior to the Final Rule, FDA gave no notice of an intent to adopt that risk/benefit test. See, 62 Fed. Reg. 30678, 62 Fed. Reg. 44247, 68 Fed. Reg. 10417, and 69 Fed. Reg. 6788. FDA violated the APA, 5 U.S.C. § 553, when it failed to give notice of its intent to create a new test for evaluating dietary supplement adulteration.

For a rule to be considered valid, an agency must provide notice in the Federal Register of its intentions to create such a rule and an opportunity for interested parties to comment on it. See e.g., U.S. v. Seward, 1981 U.S. App. LEXIS 21300 (10th Cir. 1981)(citations omitted). The APA states, in pertinent part, that prior to the issuance of a substantive rule,[15] an agency such as FDA shall provide notice of its rulemaking intentions, and such notice shall be published in the Federal Register. 5 U.S.C. § 553.[16] The APA also requires an opportunity for public participation in the rulemaking process and publication of the final rule, including a concise

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[15] A substantive rule "establishes a standard of conduct" having "the force of law." American Mining Congress v. Ray F. Marshall, 671 F.2d 1251, 1263 (10th Cir. 1982). Once codified, a substantive rule serves as a standard against which facts are later compared to determine whether certain requirements have been satisfied. Id.

[16] Adequate notice shall include "(1) a statement of time, place, and nature of public rule making proceedings, (2) reference to the legal authority under which the rule is proposed, and (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553.

statement of its basis and purpose, thirty days before its effective date. 5 U.S.C. 553 (b)-(d); see also: North American Coal Corporation v. Director, Office of Workers' Compensation Programs, 854 F.2d 386, 388 (10th Cir. 1988).

The newly enacted risk/benefit test promulgated by FDA is a substantive rule. See, American Mining Congress, 671 F.2d at 1263; see also, Pacific Gas & Electric Co. v. Federal Power Commission, 506 F.2d 33 (D.C. Cir. 1974). In future adulteration cases before FDA involving other dietary supplements and ingredients, the risks and benefits of various products will be assessed under the newly established risk/benefit test. See, 69 Fed. Reg. at 6794; see also, Remarks by Crawford, supra at p. xii-xiii.

FDA's proposed rulemaking in the Federal Register gives no indication that FDA was considering adopting its new risk/benefit test. 62 Fed. Reg. 30678, 62 Fed. Reg. 44247, 68 Fed. Reg. 10417, 69 Fed. Reg. 6788. At no time did FDA suggest that it was considering the weighing of a dietary supplement's known and reasonably likely risks against its known and reasonably likely benefits to determine whether that dietary supplement presented an unreasonable risk of illness or injury.[17] Thus, FDA violated the notice and comment requirements in 5 U.S.C. § 553.

[17] There is a general exception to the notice and comment requirement but it is not applicable here. Notice will be excused when it is shown that a proposed regulation is only an interpretative rule, a general statement of policy, or a rule of agency organization, procedure, or practice, or where an agency "for good cause finds that notice and public procedure thereon are impracticable, unnecessary or contrary to the public interest." Klaips v. Bergland, 715 F.2d 477 (10th Cir. 1983); see also 5 U.S.C. 553(b)(3)(B). The risk/benefit test is clearly not in that category.

II. THE COURT SHOULD ENJOIN THE DEFENDANTS FROM TAKING ANY ENFORCEMENT ACTION AGAINST PLAINTIFFS FOR THEIR SALE OF LOW DOSE EPHEDRA.

An injunction is commonly granted where an exclusive business has been invaded and where it is shown that an irreparable injury has been inflicted. See, Vaughan v. John C. Winston Co., 83 F.2d 370 (10th Cir. 1936). Moreover, where it is determined that an adequate remedy at law is lacking, monetary damages would be difficult and perhaps impossible to ascertain, or the invaded business would be forced to bring a series of successive lawsuits for damages to repair *the irreparable injury, an injunction will be granted.* Id. *In this case, FDA's Final Rule is invalid,* for the reasons demonstrated above, and Plaintiffs have been irreparably harmed by FDA's improper ban of their Low Dose Ephedra. Therefore, the Court should enjoin Defendants from preventing Plaintiffs from selling its Low Dose Ephedra, at least until FDA satisfies its burden of proof under the FDCA.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Honorable Court declare the Final Rule invalid in violation of the FDCA's dietary supplement safety provision, 21 U.S.C. § 342(f), and the APA, 5 U.S.C. §§ 553 and 706; remand the matter to the agency for further rulemaking consistent with the Court's opinion; and enjoin the Defendants from taking any enforcement action against Plaintiffs for their continued sale of a dietary supplement containing 10 mg or less of ephedrine alkaloids per daily dose.

DATED this 18th day of August, 2004.

Respectfully submitted,

SOLARAY, INC. AND
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CERTIFICATE OF SERVICE

I hereby certify that I caused a true and correct copy of the within and foregoing MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT to be mailed, postage prepaid, this 18th day of August, 2004, to the following:

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